



Ifw

HAND DELIVERY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Young et al.	Confirmation No.:	3135
Serial No.:	10/657,363	Art Unit:	1648
Filed:	September 8, 2003	Examiner:	Hill, Myron G.
For:	ULTRA HIGH AFFINITY NEUTRALIZING ANTIBODIES	Attorney Docket No.:	10271-159-999 (CAM: 209073-999157)

**REQUEST FOR RECONSIDERATION OF
DECISION ON PETITION UNDER 37 C.F.R. §1.78 OR, ALTERNATIVELY,
RENEWED PETITION TO ACCEPT AN UNINTENTIONALLY DELAYED CLAIM
FOR PRIORITY UNDER 37 C.F.R. §1.78**

MAIL STOP: PETITION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants received from the United States Patent and Trademark Office ("USPTO") a Decision on Petition Under 37 C.F.R. §1.78 dated June 17, 2009 ("Decision"), dismissing Applicant's Petition Under 37 C.F.R. § 1.78 filed on March 31, 2009 to accept an unintentionally delayed claim for priority ("the March 31, 2009 Petition"), which requested that the present patent application be amended to recite that it is a continuation application of U.S. Serial No. 09/771,415, filed January 26, 2001 (now U.S. Patent No. 6,656,467), which claims the benefit of U.S. Serial No. U.S. Provisional Application No. 60/178,426, filed January 27, 2000.

As required by 37 C.F.R §§ 1.78(a)(3) and 1.78(a)(6), Applicants concurrently filed in connection with the March 31, 2009 Petition, the following:

- (1) the reference required by 35 U.S.C. §§ 120 and 119(e) and 37 C.F.R. § 1.78(a)(2)(i) and 1.78(a)(5)(i) of the prior-filed application (“item (1)”);
- (2) the surcharge set forth in 37 C.F.R. § 1.17(i); and
- (3) a statement that the entire delay between the date the claim was due under 37 C.F.R. §§ 1.78(a)(2)(ii) and 1.78(a)(5)(ii) and the date the claim was filed was unintentional.

The Decision states that the March 31, 2009 Petition does not comply with item (1) above because the amendment allegedly improperly incorporated by reference the prior filed applications:

[T]he amendment is not acceptable as drafted since it improperly incorporated by reference the prior filed applications. An incorporation by reference statement added after an application’s filing date is not effective because no new matter can be added to an application after its filing date (*see* 35 U.S.C. § 132(a)). If an incorporation by reference statement is included in an amendment to the specification to add a benefit claim under 35 U.S.C. § 120 after the filing date of the application, the amendment would not be proper. When a benefit claim under 35 U.S.C. § 120 is submitted after the filing of an application, the reference to the prior application cannot include an incorporation by reference statement of the prior application. See Dart Industries v. Banner, 636 F.2d 684; 207 USPQ 273 (C.A.D.C. 1980). *Note* MPEP §§ 201.06(c) and 608.04(b).

(Decision, pages 1-2).

Applicants respectfully disagree with the Decision for the reasons set forth below. In particular, Applicants direct the Petitions Examiner’s attention to MPEP §201.06(c), which was cited in the Decision, which states that such an incorporation by reference statement may appear in the transmittal letter or specification:

An applicant may incorporate by reference the prior application by including, in the continuation or divisional application-as-filed, an explicit statement that such specifically enumerated prior application or applications are “hereby incorporated by reference.” The statement must appear in the specification. See 37 CFR 1.57(b) (b) and MPEP § 608.01(p). The inclusion of this incorporation by reference statement will permit an applicant to amend the continuation or divisional application to include subject matter from the prior application(s), without the need for a petition provided the continuation or divisional application is entitled to a filing date notwithstanding the incorporation by reference. For applications filed prior to September 21, 2004, the incorporation by reference statement may appear in the transmittal letter or in the specification. Note that for applications filed prior to September 21, 2004, if applicants used a former version of the transmittal letter form provided by the USPTO, the incorporation by reference statement could only be relied upon to add inadvertently omitted material to the continuation or divisional application.

(MPEP § 201.06(c)(iv); emphasis added). The present application was filed on September 8, 2003 and thus qualifies as an application “filed prior to September 21, 2004.” In addition, the transmittal letter filed on September 8, 2003 (“Transmittal Letter”) (Appendix A) with the present application explicitly stated that “[t]his application is a continuation of U.S. Application Serial No. 09/771,415, filed 28 January 2001, which is based on U.S. Provisional Application No. 60/178,426, filed 27 January 2000, the disclosures of which are hereby incorporated by reference in their entirety” (Transmittal Letter at page 2; emphasis added). Thus, Applicants respectfully submit that an amendment to the specification incorporating by reference each priority application does not introduce new matter because this incorporation by reference was already included in the Transmittal Letter concurrently filed on September 8, 2003 with the present application.

In view of the foregoing, Applicants respectfully request reconsideration of the USPTO’s decision on the March 31, 2009 Petition and reiterate their request to enter the Amendment that

was concurrently filed with the March 31, 2009 Petition (Appendix B), such that the specification is amended as follows:

This application is a continuation of U.S. Serial No. 09/771,415, filed January 26, 2001 (now U.S. Patent No. 6,656,467), which claims ~~priority~~ the benefit of U.S. Provisional Application Serial No. 60/178,426, filed 27 January 27, 2000, the disclosure of each of which is hereby incorporated by reference in its entirety.

However, should the Petitions Examiner continue to disagree and remain of the opinion that the Amendment filed on March 31, 2009 fails to comply with item (1) above, Applicants respectfully request a Renewed Petition under 37 C.F.R. § 1.78(a)(3) and entry of the alternative Amendment filed herewith as Appendix C to correct allegedly omitted item (1) from the March 31, 2009 Petition, such that the first paragraph of the specification paragraph instead reads:

This application is a continuation of U.S. Serial No. 09/771,415, filed January 26, 2001 (now U.S. Patent No. 6,656,467), which claims the benefit of U.S. Provisional Application Serial No. 60/178,426, filed January 27, 2000, wherein the disclosure of ~~each of which~~ said provisional is hereby incorporated by reference in its entirety.

Applicants note that the incorporation by reference of the provisional application was included in the first paragraph of the application as filed on September 8, 2003 (Exhibit D) and, thus, does not constitute new matter.

Second Request for Filing Receipt

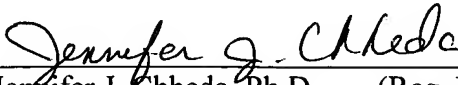
Since a Filing Receipt still has not yet been received in connection with the above-identified patent application, Applicants once again request that the Patent Office issue a Filing Receipt listing that the above-identified application is a continuation application of U.S. Serial No. 09/771,415, filed January 26, 2001 (now U.S. Patent No. 6,656,467), which claims the benefit of U.S. Serial No. U.S. Provisional Application No. 60/178,426, filed January 27, 2000.

U.S. Serial No. 10/657,363
Request for Reconsideration of
Decision on Petition Under 37 C.F.R. §1.78
August 13, 2009
Page 5 of 5

Applicants believe that no fee is due for this request. However, should any fee(s) be required, the Commissioner is authorized to charge the required fee(s) or credit any overpayment to Jones Day Deposit Account 50-3013.

Respectfully submitted,

Date: August 13, 2009


Jennifer J. Chheda, Ph.D. (Reg. No. 46,617)

For: Anthony M. Insogna (Reg. No. 35,203)
JONES DAY
222 East 41st Street
New York, NY 10017-6702
(858) 314-1200

Attachments (Appendices A-D)

U.S. Serial No. 10/657,363
Request for Reconsideration of
Decision on Petition Under 37 C.F.R. §1.78
August 13, 2009
Appendix A



APPENDIX A

Transmittal Letter for U.S. Serial No. 10/657,363 filed September 8, 2003

COPY



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Young et al
Serial No: Unassigned Art Unit: 1648
Filed: Herewith Examiner: Foley, S.
Title: ULTRA HIGH AFFINITY NEUTRALIZING ANTIBODIES
Docket No: 469201-689

8 September 2003

Commissioner for Patents
U.S. Patent and Trademark Office
Washington, D.C. 20231

MAIL STOP: PATENT APPLICATION

TRANSMITTAL OF CONTINUATION APPLICATION UNDER 37 C.F.R. 1.53(b)

Sir:

Transmitted herewith for filing is a Continuation Application of U.S. Application 09/771,415, filed 26 January 2001, still pending, of inventors:

James F. Young, Leslie S. Johnson, William D. Huse, Herren Wu and Jeffry D. Watkins

entitled: Ultra High Affinity Neutralizing Antibodies

Enclosed with the application are:

1. Application (51 sheets), Paper Sequence Listing (12 sheets);
2. Formal Drawings (10 sheets);



COPY

Serial No.
Filed: 8 September 2003

3. Copy of Declaration of Parent Application (executed – 3 sheets);
4. Information Disclosure Statement;
5. Form 1449 and Notices of References Cited (8 sheets);
6. Copy of Sequence Listing in Computer Readable Form (3.5" diskette);
7. Statement Under 37 C.F.R. 1.821(f);
8. Check \$1254.00; and
9. Self-addressed, Postage paid, return receipt postcard.

The fee has been calculated as follows **ON THE BASIS THAT APPLICANT IS A LARGE ENTITY** and in view of the claims added herewith by Preliminary Amendment:

	<u>Number of Claims Filed</u>	<u>Extra Claims</u>		<u>Rate</u>	<u>Fee</u>
Basic Fee				\$750	\$750
Total Claims	48 - 20 =	28	X	\$ 18	\$504
Indep. Claims	2 - 3 =	0	X	\$ 84	\$
TOTAL:					\$1254

REMARKS

This application is a continuation of U.S. Application Serial No. 09/771,415, filed 26 January 2001, which is based on U.S. Provisional Application No. 60/178,426, filed 27 January 2000, the disclosures of which are hereby incorporated by reference in their entirety.

In addition, Applicants file herewith a copy of the Declaration and Power of Attorney filed in the parent application.

COPY

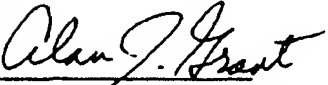
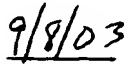
Serial No.

Filed: 8 September 2003



Applicants also file herewith an Information Disclosure Statement along with copies of forms 1449 and Notices of References Cited in the parent application. Applicant will supply copies of these references to the Examiner upon request but they should all be included in the parent file history.

The Commissioner is authorized to charge payment of any additional filing fees required with this communication or credit any overpayment to Deposit Account No. 03-0678.

<p align="center"><u>EXPRESS MAIL CERTIFICATE</u></p> <p>Express Mail Label No. EU129666084US</p> <p>Deposit Date: 8 September 2003</p> <p>I hereby certify that this paper and the attachments hereto are being deposited today with the U.S. Postal Service "Express Mail Post Office To Addressee" service under 37 CFR 1.10 on the date indicated above addressed to:</p> <p align="center">Commissioner for Patents U.S. Patent and Trademark Office Washington, D.C. 20231</p> <p> Alan J. Grant, Esq.</p> <p> Date</p>

Respectfully submitted,



Alan J. Grant, Esq.
Reg. No. 33,389
CARELLA, BYRNE, BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN
6 Becker Farm Road
Roseland, NJ 07068
Tel. No.: (973) 994-1700

U.S. Serial No. 10/657,363
Request for Reconsideration of
Decision on Petition Under 37 C.F.R. §1.78
August 13, 2009
Appendix B



APPENDIX B

Amendment filed with the March 31, 2009 Petition

COPY

eFile

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Young et al.	Confirmation No.:	3135
Serial No.:	10/657,363	Art Unit:	1648
Filed:	September 8, 2003	Examiner:	Hill, Myron G.
For:	ULTRA HIGH AFFINITY NEUTRALIZING ANTIBODIES	Attorney Docket No.:	10271-159-999 (CAM: 209073-999157)

AMENDMENT

MAIL STOP: AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

A Notice of Allowance and Fee(s) Due was mailed on December 31, 2008 for which a response is due on March 31, 2009. In lieu of an Issue Fee payment, Applicants are submitting herewith the following documents via EFS-web: (a) Request for Continued Examination (RCE) Transmittal; (b) a Petition to Accept an Unintentionally Delayed Claim for Priority Under 37 C.F.R. § 1.78; (c) a Supplemental Information Disclosure Statement, (d) a List of References Cited by Applicant, and (e) copies of References K01-K30 and L01-L58. Thus, these papers are timely filed.

Applicants respectfully request consideration and entry of the following amendments and remarks.

Amendments to the Specification begin on page 2 of this paper.

Remarks begin on page 3 of this paper.

U.S. Serial No. 10/657,363
Amendment
March 31, 2009
Page 2 of 4

COPY

AMENDMENTS TO THE SPECIFICATION:

On page 1, please replace the paragraph spanning lines 6-8 with the following paragraph:

This application is a continuation of U.S. Serial No. 09/771,415, filed January 26, 2001
(now U.S. Patent No. 6,656,467), which claims ~~priority~~ the benefit of U.S. Provisional
Application Serial No. 60/178,426, filed ~~27~~ January 27, 2000, the disclosure of each of which is
hereby incorporated by reference in its entirety.

COPY

REMARKS

I. Amendments to the Specification

The allowance of pending claims 86-111 is gratefully acknowledged. However, upon review of the file history by the undersigned Attorney for Applicants on March 30, 2009 in connection with the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) that was mailed with the Notice of Allowability on December 31, 2008, it was noticed that: (a) the proper continuity data was included on the Transmittal Letter filed on September 8, 2003, which indicated that each application was incorporated by reference in its entirety, but was not thereafter submitted by way of Amendment or Application Data Sheet as required by 37 C.F.R. § 1.78(b)(3); (b) no Official Filing Receipt was ever mailed by the U.S. Patent and Trademark Office; and (c) the above-referenced patent application published as U.S. Publication No. 2004-0131609A1 and listed the correct continuity data on the face of the published document (*i.e.*, a continuation application of U.S. Serial No. 09/771,415, filed January 26, 2001, which claims the benefit of U.S. Serial No. U.S. Provisional Application No. 60/178,426, filed January 27, 2000).

As such, due to the conflicting information in the file, Applicants have amended the specification herein to confirm and update the claim to priority, and Applicants are also filing concurrently herewith a Petition to Accept an Unintentionally Delayed Claim for Priority Under 37 C.F.R. § 1.78, with provisions for the required fees. No new matter has been added by way of this amendment.

Entry of this amendment and grant of the Petition filed herewith is respectfully requested.

II. Request for Filing Receipt

Since a Filing Receipt has not yet been received in connection with the above-identified patent application, Applicants request that the Patent Office issue a Filing Receipt listing that the above-identified application is a continuation application of U.S. Serial No. 09/771,415, filed January 26, 2001 (now U.S. Patent No. 6,656,467), which claims the benefit of U.S. Serial No. U.S. Provisional Application No. 60/178,426, filed January 27, 2000.

COPY


III. Conclusion

In view of the foregoing remarks, Applicants respectfully submit that this application is (again) in condition for immediate allowance. If the Examiner disagrees, it is requested that the Examiner call the undersigned at the number listed below to arrange a telephone interview to expedite prosecution of the application.

Applicants believe no additional fees are due in connection with this Amendment. However, if there are any other fees due, please charge them to Jones Day Deposit Account 50-3013. Also, please charge any fees underpaid or credit any fees overpaid to the same Deposit Account.

Respectfully submitted,




Tamera M. Weisser, Ph.D. (Reg. No. 47,856)

Date: March 31, 2009

For: Anthony M. Insogna (Reg. No. 35,203)
JONES DAY
222 East 41st Street
New York, NY 10017-6702
(858) 314-1200

U.S. Serial No. 10/657,363
Request for Reconsideration of
Decision on Petition Under 37 C.F.R. §1.78
August 13, 2009
Appendix C



APPENDIX C

Alternative Amendment for Consideration by Petitions Examiner



HAND DELIVERY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Young et al.	Confirmation No.:	3135
Serial No.:	10/657,363	Art Unit:	1648
Filed:	September 8, 2003	Examiner:	Hill, Myron G.
For:	ULTRA HIGH AFFINITY NEUTRALIZING ANTIBODIES	Attorney Docket No.:	10271-159-999 (CAM: 209073-999157)

AMENDMENT

MAIL STOP: AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In conjunction with the Renewed Petition to Accept an Unintentionally Delayed Claim for Priority under 37 C.F.R. §1.78 filed herewith in connection with the above-referenced application, Applicants respectfully request consideration and entry of the following amendments and remarks.

Amendments to the Specification begin on page 2 of this paper.

Remarks begin on page 3 of this paper.

AMENDMENTS TO THE SPECIFICATION:

On page 1, please replace the paragraph spanning lines 6-8 with the following paragraph:

This application is a continuation of U.S. Serial No. 09/771,415, filed January 26, 2001 (now U.S. Patent No. 6,656,467), which claims priority the benefit of U.S. Provisional Application Serial No. 60/178,426, filed 27 January 27, 2000, wherein the disclosure of which said provisional is hereby incorporated by reference in its entirety.

REMARKS

I. Amendments to the Specification

Upon review of the file history by the undersigned Attorney for Applicants on March 30, 2009 in connection with the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) that was mailed with the Notice of Allowability on December 31, 2008, it was noticed that: (a) the proper continuity data was included on the Transmittal Letter filed on September 8, 2003, which indicated that each application was incorporated by reference in its entirety, but was not thereafter submitted by way of Amendment or Application Data Sheet as required by 37 C.F.R. § 1.78(b)(3); (b) no Official Filing Receipt was ever mailed by the U.S. Patent and Trademark Office; and (c) the above-referenced patent application published as U.S. Publication No. 2004-0131609A1 and listed the correct continuity data on the face of the published document (*i.e.*, a continuation application of U.S. Serial No. 09/771,415, filed January 26, 2001, which claims the benefit of U.S. Serial No. U.S. Provisional Application No. 60/178,426, filed January 27, 2000).

As such, due to the conflicting information in the file, Applicants filed on March 31, 2009 a Petition Under 37 C.F.R. § 1.78 to Accept an Unintentionally Delayed Claim for Priority (“the March 31, 2009 Petition”). Thereafter, Applicants received from the United States Patent and Trademark Office (“USPTO”) a Decision on Petition Under 37 C.F.R. § 1.78 dated June 17, 2009 (“Decision”), dismissing the March 31, 2009 Petition, as allegedly omitting the reference required by 35 U.S.C. §§ 120 and 119(e) and 37 C.F.R. § 1.78(a)(2)(i) and 1.78(a)(5)(i) of the prior-filed application (“item (1)”).

As such, and in connection with the Renewed Petition to Accept an Unintentionally Delayed Claim for Priority under 37 C.F.R. § 1.78 filed herewith, Applicants have amended the specification herein to confirm and update the claim to priority. No new matter has been added by way of this amendment. Applicants note that the incorporation by reference of the provisional application was included in the first paragraph of the application as filed on September 8, 2003 and, thus, does not constitute new matter.

Entry of this amendment and grant of the Renewed Petition filed herewith is respectfully requested.

II. Second Request for Filing Receipt

Since a Filing Receipt still has not yet been received in connection with the above-identified patent application, Applicants once again request that the Patent Office issue a Filing Receipt listing that the above-identified application is a continuation application of U.S. Serial No. 09/771,415, filed January 26, 2001 (now U.S. Patent No. 6,656,467), which claims the benefit of U.S. Serial No. U.S. Provisional Application No. 60/178,426, filed January 27, 2000.

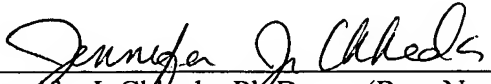
III. Conclusion

If the Renewed Petition is granted and the Amendment provided herein is entered, Applicants respectfully submit that this application is (again) in condition for immediate allowance.

Applicants believe no additional fees are due in connection with this Amendment. However, if there are any other fees due, please charge them to Jones Day Deposit Account 50-3013. Also, please charge any fees underpaid or credit any fees overpaid to the same Deposit Account.

Respectfully submitted,

Date: August 13, 2009


Jennifer J. Chheda, Ph.D. (Reg. No. 46,617)

For: Anthony M. Insogna (Reg. No. 35,203)
JONES DAY
222 East 41st Street
New York, NY 10017-6702
(858) 314-1200

U.S. Serial No. 10/657,363
Request for Reconsideration of
Decision on Petition Under 37 C.F.R. §1.78
August 13, 2009
Appendix D

APPENDIX D

First Page of U.S. Serial No. 10/657,363 as Filed on September 8, 2003



ULTRA HIGH AFFINITY NEUTRALIZING ANTIBODIES

5

This application claims priority of U.S. Provisional Application Serial No. 60/178,426, filed 27 January 2000, the disclosure of which is hereby incorporated by reference in its entirety.

10

BACKGROUND OF THE INVENTION

15

The present invention relates to novel ultra high affinity neutralizing antibodies.

20

The current incidence of infection caused by resistant or difficult to control microbes has created a need for newer approaches to controlling such organisms, as well as to treating those already infected.

25

Among the more difficult infectious agents to control and treat are the viruses. For example, respiratory syncytial virus (RSV) is the major cause of acute respiratory illness in young children admitted to hospitals and the major cause of lower respiratory tract infection in young children. A major obstacle to producing an effective vaccine against such agents as RSV has been the issue of safety. Conversely, the use of immunoglobulins against such viral agents has proven of some value. For example, studies have shown that high-titred RSV immunoglobulin was effective both in prophylaxis and therapy for RSV infections in animal models.

30

An alternative approach has been the development of antibodies, especially neutralizing monoclonal antibodies, with high specific neutralizing

35